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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517
30565	7590	10/11/2007		
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 10/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/666,900

Applicant(s)

MCKAY ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 27 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 27 and 42-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

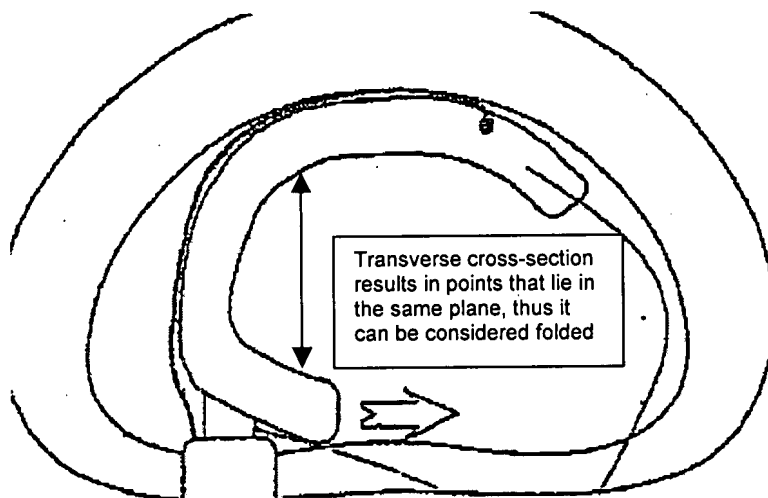
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17,27 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambrecht et al. (2002/151979). Fig. 49G illustrates an intervertebral disc implant **400** having a length and first straight configuration with a drawstring **406** attached thereto for folding the implant in the disc space. Figs. 49C,E, 50C then shows how the implant is then manipulated to a folded second configuration. See example below.



Lambrecht et al.

disclose the implant material can be in a woven form, paragraph 209. The examiner is interpreting the claimed elements "braided" in this way: both braided and woven are interlaced strands or filaments. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Figs. 50C,50D,51B,51C

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show the implant being pulled to a folded configuration. Lambrecht also discloses the drawstring is used to pull the implant to a folded configuration, paragraph 207.

Lambrecht additionally disclose natural tissue material is used for the implant, paragraphs 31,32.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42,45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979). Lambrecht et al. is explained supra. Lambrecht shows (Fig. 49G) an implant with a length greater than the width. However, Lambrecht et al. do not explicitly state the implant has a length-to-width ratio of less than 5:1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize or vary the dimensions of the implant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable dimensions involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With respect to claims 45-47, it is noted that Lambrecht discloses that multiple sites on the implant can be used to pass the drawstring through, paragraph 207. However, Lambrecht does not explicitly disclose the number of sites to pass the drawstring through. It would have been an obvious matter of design choice to modify the number of sites on the implant for the drawstring, since applicant has not disclosed that using three, five or ten provide any advantage, or solve a stated problem, or are used for any

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particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the multiple sites on the implant taught by Lambrecht or the claimed three, five or ten in claim(s) 45-47 respectively because both implant devices are pulled in the same fashion with multiple drawstring locations.

Claims 18,43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979) in view of Muhanna (6936070). Lambrecht et al. is explained above. However, Lambrecht et al. fail to disclose the natural tissue is pericardium. Muhanna discloses that natural pericardium tissue can be used to form a spinal implant material, col. 4, lines 51-54. It would have been obvious to one of ordinary skill in the art to substitute natural tissue and use pericardium as taught by Muhanna for the natural tissue in Lambrecht et al. spinal implant because of the abundance, availability and biocompatibility.

Claims 19,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht et al. (2002/151979) in view of Sybert et al. (2002/107570). Lambrecht et al. is explained above. However, Lambrecht et al. fail to disclose the natural tissue is SIS. Sybert et al. discloses that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Lambrecht et al. spinal implant because of the abundance of SIS and its durability.

Response to Arguments

Applicant's arguments filed 7/26/07 have been fully considered but they are not persuasive. Applicant argues that the Lambrecht reference does not "appear" to

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disclose folding the tissue in the intervertebral disc or nucleus. However, as mentioned above, Lambrecht clearly illustrates (Fig. 49C,E, 50C) the tissue implant can be folded and is manipulated by pulling (as admitted by Applicant, p.6 of amendment). Since tissue implants are inherently flexible or pliable, the control filament or "drawstring" attached to Lambrecht's tissue implant is fully capable of being effective to fold the tissue implant. Applicant also argues that the pulling is not done after implanting the device, however, as mentioned in the reference and admitted by the Applicant on page 6 of the response, paragraphs 207,208 clearly state the implant is pulled once it is implanted.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (7:30am-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.

TC 3700, AU 3738